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AdvaMed
Advanced Medical Technology Association

June 26, 2003

The Honorable Earl Pomeroy
Ways and Mean Committee
U.S. House of Representatives
1110 Longworth House Office Building
Washington, DC 20515-3401

Dear Congressman Pomeroy:

On behalf of America's medical technology companies and the patients we serve, I want to thank you for your continued commitment to ensuring that Medicare beneficiaries have access to the new medical technologies they need. AdvaMed strongly supports H.R. 1, the "Medicare Modernization and Prescription Drug Act of 2003."

AdvaMed represents over 1100 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members are devoted to helping patients lead longer, healthier and more productive lives through the development of new lifesaving and life-enhancing technologies.

AdvaMed supports the provisions in the bill to promote greater competition and innovation within the Medicare program so seniors and people with disabilities can choose a benefits package that best suits their needs. AdvaMed supports increased private health plan participation within Medicare and the use of market-based pricing, rather than reliance on fee-schedules. We also support full disclosure of health plan coverage policies and transparent processes for making coverage determinations.

In addition, we support important provisions in the bill to reduce the delays of 15 months to five years that seniors and people with disabilities currently enrolled in Medicare face in accessing breakthrough medical technologies after FDA approval. While Congress and the Centers for Medicare and Medicaid Services (CMS) have taken steps over the past three years to address these delays, serious access barriers remain**.**

Specifically, the Medicare Modernization and Prescription Drug Act builds on reforms included in the Medicare Innovation Responsiveness Act (H.R. 941) introduced by Reps. Ramstad, Eshoo (D-CA), and Pitts (R-PA) to reduce patient access delays to innovative medical technologies by:

- Reforming reimbursements for breakthrough technologies used in the inpatient setting. Building on the unmet intent of legislation enacted in BIPA to provide adequate payment for breakthrough technologies, the bill would require an add-on payment to cover the additional costs of a new technology. CMS has interpreted the law passed by Congress so narrowly that no new medical device has qualified.

- Improving Medicare beneficiary access to clinical trials by requiring Medicare to cover the routine costs of clinical trials for procedures involving breakthrough medical technologies like heart assist devices. Currently, Medicare pays for routine costs for nearly all drug and most device trials, but fails to cover routine costs for procedures involving breakthrough medical technologies.

- Creating a Medicare Council for Technology and Innovation that would encourage better coordination and accountability within the Centers for Medicare and Medicaid Services. By providing a single point of contact at CMS for medical technology issues, this Council will be especially helpful to the thousands of small companies developing new breakthroughs as they seek to make these advances available to America's seniors and people with disabilities.

- Establishing 9-12 month deadlines for Medicare to fully implement coverage, coding and payment for new medical technologies subject to a national coverage decision.

- Reforming temporary national codes so they may be used to replace local codes, which will expire in December 2003.

- Allowing CMS to consider adoption of the International Classification of Disease, 10th Edition (ICD-10), a critically needed new coding system for the inpatient hospital setting to improve data collection.

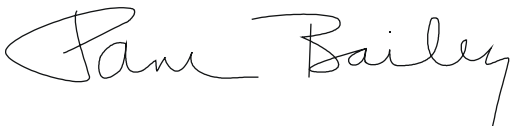
In addition, the bill adopts provisions of a bill introduced by Reps. Dunn (R-WA), McDermott (D-WA), Ferguson (R-NJ) and Deutsch (D-FL) (H.R. 569) to improve access to new diagnostic tests that can detect diseases earlier and more accurately by establishing a transparent, predictable process for setting Medicare reimbursement rates for these technologies. These provisions adopt recommendations made in a 2000 Institute of Medicine report.

AdvaMed also supports the provisions in the bill to encourage the use of remote monitoring technologies that enable patient disease management through the automatic collection and exchange of pertinent clinical and personal information within the Medicare program. Keeping patients healthier through key management programs will be better for the patient, and more cost-effective to the health care system. The industry also appreciates your efforts to promote the adoption of information technologies for use by health care providers, which will help providers be more efficient in the delivery of care and help reduce errors within the system.

AdvaMed supports these provisions, but we have concerns about language in the package to give CMS broad new authority to enter into competitive bidding contracts to purchase certain products, including durable medical equipment. We believe it is premature to impose competitive bidding on a national scale without fully assessing CMS' limited experience in this area. However, if the committee advances this proposal, we urge it to include basic safeguards to ensure patient access to the latest innovations and due process in the bidding process.

Thank you again for your commitment to America's 40 million Medicare beneficiaries and to ensuring they have access to the life-saving and life improving innovations they need.

Truly yours,



Pamela G. Bailey
President